IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

ASAHI KASEI PHARMA CORPORATION,

Plaintiff,

v.

ACTELION LTD., *et al.*,

Defendants.
_____/

No. C 09-405 SI

ORDER GRANTING PLAINTIFF'S MOTION TO REMAND

On March 20, 2009, the Court heard argument on plaintiff's motion to remand and defendants' motion to dismiss for lack of personal jurisdiction. As set forth below, the Court concludes that removal was improper, and GRANTS plaintiff's motion to remand. As such, the Court does not review the merits of defendants' motion to dismiss.

BACKGROUND

Plaintiff Asahi Kasei Pharma Corporation is a Japanese pharmaceutical corporation that develops and manufactures a range of pharmaceutical products and medical devices. Compl. ¶ 3. In June 2006, Asahi entered into a license agreement with defendant CoTherix for the development and marketing of Fasudil, a promising new drug compound discovered by Asahi for the treatment of pulmonary arterial hypertension ("PAH") and stable angina. *Id.* ¶ 1. Asahi alleges that defendant Actelion[1] interfered with

[1] Asahi has sued several Actelion entities: Actelion Ltd., Actelion Pharmaceuticals, Ltd., Actelion Pharmaceuticals, US, Inc., and Actelion US Holding Company. Two of these entities, Actelion Ltd. and Actelion Pharmaceuticals, Ltd., are Swiss corporations, and they have separately moved to dismiss for lack of personal jurisdiction. Actelion Pharmaceuticals, US, Inc., is a Delaware corporation

the license agreement, or in the alternative, assumed and then breached the license agreement between Asahi and CoTherix in order to preserve and extend Actelion's monopoly in the market for treatment of PAH. *Id.*

Asahi alleges that in November 2006, Actelion acquired CoTherix, and paid a "massive premium" to do so "both because the acquisition allowed Actelion to extend sales of Tracleer [Actelion's treatment for PAH] and, at the same time, delay and/or eliminate Fasudil as a competitive medication." *Id.* ¶ 14. After Actelion's acquisition of CoTherix was completed, Actelion wrote to Asahi "purportedly on behalf of CoTherix" and provided notice of its intent to halt CoTherix's development of Fasudil "'for – *inter alia* – business and commercial reasons, including other pipeline considerations.'" *Id.* ¶ 15 (quoting notice). Asahi alleges that "the purpose of the takeover was to prevent a challenge to Actelion's Tracleer monopoly by Fasudil and to exploit synergies between Tracleer and Ventavis [CoTherix's treatment for PAH]. By embracing new competitive treatments as 'complementary' therapies with Tracleer, and heavily promoting the combined use of two drugs, Actelion hoped to grow Tracleer sales." *Id.* ¶ 35. Asahi alleges that it has been unable to find a new development partner, and, as a result, the project is on hold until a new partner is found. *Id.* ¶ 18. Asahi also alleges that the development of Fasudil in Japan will "inevitably" be delayed because Asahi cannot use data from the U.S. clinical trials in its regulatory submissions in Japan. *Id.*

On November 19, 2008, Asahi filed suit against Actelion and CoTherix in the Superior Court for the County of San Mateo. Asahi alleges seven claims for relief against defendants: (1) intentional interference with contract; (2) intentional and/or negligent interference with prospective economic advantage; (3) breach of contract; (4) declaratory relief re: alter ego liability; (5) violation of Cal. Bus. & Prof. Code § 16700 (California Cartwright Act); (6) violation of Cal. Bus. & Prof. Code § 17500 (California's False Advertising Law); and (7) violation of Cal. Bus.& Prof. Code § 17200 (California's Unfair Competition Law). Asahi did not file the lawsuit as a class action, and seeks damages, injunctive and declaratory relief. Asahi's False Advertising and Unfair Competition claims allege, *inter alia*, that

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with its principal place of business in South San Francisco. Compl. ¶ 23. The distinctions between the different Actelion entities are not relevant to the motion to remand, and thus the Court will refer to "Actelion" to mean all of the Actelion defendants.

defendants advertised Tracleer and Ventavis as a combined therapy for PAH using false or misleading statements of fact regarding the drugs, and that defendants have promoted "off-label" combination therapy of the two drugs to physicians, hospitals, and other medical professionals. *Id.* ¶ 63.

Actelion Pharmaceuticals US, Inc. removed the case to this Court asserting jurisdiction under the Class Action Fairness Act ("CAFA"), 28 U.S.C. § 1332(d), and under 28 U.S.C. §§ 1331 and 1441 because "Plaintiff's claims are not only inextricably intertwined with, but also arise from, implicitly alleged violations of federal statutes and regulations." Notice of Removal at 5. Actelion contends that "In essence, Plaintiff alleges that Defendant Actelion Pharmaceuticals US, Inc. promoted two Food & Drug Administration ("FDA") approved products, Tracleer and Ventavis, in violation of the federal Food, Drug & Cosmetic Act, 21 U.S.C. § 301 *et seq.*, and its implementing regulations." *Id.*

LEGAL STANDARD

Generally, a state court action is only removable to federal court if it might have been brought there originally. 28 U.S.C. § 1441(a). The federal removal statute is strictly construed, and federal courts reject jurisdiction if there is any doubt as to whether removal was proper. *Duncan v. Stuetzle*, 76 F.3d 1480, 1485 (9th Cir. 1996). Federal law requires that the notice of removal of a civil action must be filed within 30 days after service. 28 U.S.C. § 1446(b). The party seeking removal bears the burden of proving its propriety. *Duncan*, 76 F.3d at 1485; *Abrego Abrego v. The Dow Chem. Co.*, 443 F.3d 676, 683-85 (9th Cir. 2006).

Existence of federal jurisdiction on removal must be determined on the face of the complaint. *See Louisville & Nashville R.R. v. Mottley*, 211 U.S. 149 (1908). A "cause of action arises under federal law only when the plaintiff's well pleaded complaint raises issues of federal law." *Metropolitan Life Ins. Co. v. Taylor*, 481 U.S. 58, 63 (1987). However, the Court may examine the entire record to determine if the real nature of the claim is federal, notwithstanding plaintiff's characterization to the contrary, when the plaintiff has, by "artful pleading," attempted to defeat defendant's right to a federal forum. *See Federated Dep't Stores, Inc. v. Moitie*, 452 U.S. 394, 397 n.2 (1981). A complainant cannot "avoid federal jurisdiction simply by omitting from the complaint federal law essential to his claim, or by casting in state law terms a claim that can be made only under federal law." *Harper v. San Diego*

Transit Corp., 764 F.2d 663, 666 (9th Cir. 1985).

DISCUSSION

I. Class Action Fairness Act (CAFA)

Defendants contend that removal was proper under CAFA because Asahi's False Advertising and Unfair Competition claims are brought as representative claims on behalf of a nationwide class of "consumers." Defendants rely on the following allegations in the complaint: (1) "Defendants' false or misleading statements or omissions actually deceive, or have the potential to deceive, a substantial segment of consumers, or potential consumers." Compl. ¶ 97; (2) "Asahi and consumers have been injured by these false and misleading statements." *Id*. ¶ 98; and (3) "The relevant geographic market is the United States." *Id*. ¶ 52.

Plaintiff contends that CAFA is not a basis for removal because the lawsuit was not brought as a class or representative action, and the False Advertising and Unfair Competition claims are brought solely on behalf of Asahi. Plaintiff correctly notes that both statutes provide that a "corporation" is a proper plaintiff. *See* Cal. Bus. & Prof. Code §§ 17535 (FAL); 17204 (UCL); *see also Aron v. U-Haul Co. of California*, 143 Cal. App. 4th 796, 803 (2006) ("Because the allegations set forth a basis for a claim of actual economic injury as a result of an unfair and illegal business practice, Aron has standing."). Plaintiff argues that the complaint's reference to "consumers" does not convert the complaint into a class or representative action, and plaintiff emphasizes the fact that the complaint only seeks relief on behalf of Asahi. In addition, the complaint's allegation that the "relevant geographic market is the United States" is within the context of the Cartwright Act claim, which again is brought only on behalf of Asahi.

The Court agrees with plaintiff that there is no removal jurisdiction under CAFA.[2] Defendants

[2] Relying on legislative history, defendants assert that CAFA's provisions should be "construed broadly in favor of finding jurisdiction." Opposition at 8-9. To the extent defendants suggest that they do not have the burden of demonstrating that removal under CAFA was proper, this assertion has been rejected by the Ninth Circuit. *See Abrego Abrego v. The Dow Chemical Co.*, 443 F.3d 676, 685-86 (9th Cir. 2006) (examining CAFA's language and legislative history to conclude that "CAFA's silence, coupled with a sentence in a legislative committee report untethered to any statutory language, does not alter the longstanding rule that the party seeking federal jurisdiction on removal bears the burden of

do not cite any authority for the novel proposition that the FAL and UCL claims, which are expressly brought only on behalf of Asahi and which seek relief only for Asahi, are transformed into representative claims simply because the complaint alleges that defendants have also harmed consumers. Defendants' reliance on *Friedman v. 24 Hour Fitness USA, Inc.*, 580 F. Supp. 2d 985, 994 (C.D. Cal. 2008), is unavailing because *Friedman* did not address the question presented here. Instead, *Friedman* held that after Proposition 64 eliminated UCL lawsuits on behalf of the general public, a plaintiff may bring a UCL representative claim only if he also meets class action requirements. *Id*. Here, unlike the complaint in *Friedman*, the UCL claim is not brought "on behalf of the general public." Because this case is not a class action, or a class action in disguise, there is no basis for removal under CAFA.

II. Arising under federal law

Defendants also contend that plaintiff's claims arise under federal law because they are inextricably intertwined with, and arise from, implicitly alleged violations of the federal Food, Drug & Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, and its implementing regulations. Defendants argue that in order to adjudicate plaintiff's UCL and FAL claims, it will be necessary to resolve plaintiff's allegation that defendants have promoted Tracleer and Ventavis as an "off-label" combination therapy.

To determine whether plaintiff's state law claims actually arise under federal law, the Court must determine whether the "state-law claim necessarily raise[s] a stated federal issue, actually disputed and substantial, which a federal forum may entertain without disturbing any congressionally approved balance of federal and state judicial responsibilities." *Grable & Sons Metal Prods., Inc. v. Darue Eng'g & Mfg.*, 545 U.S. 308, 314 (2005). Plaintiff contends that the complaint's references to the FDCA serve only as evidence of defendants' liability but do not function as a necessary element of the UCL and FAL claims. Plaintiffs rely on *Merrell Dow Pharmaceuticals, Inc. v. Thompson*, 478 U.S. 804 (1986), in which the Supreme Court held that a consumers' state court action against a drug manufacturer, based

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establishing that jurisdiction.").

in part on the theory that the manufacturer's alleged violation of the FDCA constituted negligence,[3] did not present a federal question, and thus removal was improper. The Supreme Court found it significant that there was no private right of action under the FDCA, noting that it would "flout, or at least undermine, congressional intent to conclude that the federal courts might nevertheless exercise federal-question jurisdiction and provide remedies for violations of that federal statute solely because the violation of the federal statute is said to be a 'rebuttable presumption' or a 'proximate cause' under state law, rather than a federal action under federal law." *Id*. at 812. The Court rejected the contention that the violation of the FDCA was a necessary element of the consumer plaintiffs' state law negligence claim: "Given the significance of the assumed congressional determination to preclude federal private remedies, the presence of the federal issue as an element of the state tort is not the kind of adjudication for which jurisdiction would serve congressional purposes and the federal system." *Id*.

Here, as in *Merrell Dow*, the alleged FDCA violations are not essential to plaintiff's UCL and FAL claims. Plaintiff alleges that defendants have falsely advertised and promoted the use of Tracleer and Ventavis as a "perfect fit" and "a logical combination," "even though studies regarding the combination therapy were still underway and no FDA approval had been sought or obtained for the combined use of the two drugs." Compl. ¶ 62. The truth or falsity of defendants' statements regarding the two drugs can be determined without reference to or interpretation of the FDCA. The alleged "off-label" violations of the FDCA would be evidence of defendants' liability under the UCL and FAL claims, but are not essential elements of those claims. *See Grable*, 545 U.S. at 319 (explaining *Merrell Dow* and noting that "[a] general rule of exercising federal jurisdiction over state claims resting on federal mislabeling and other statutory violations would thus have heralded a potentially enormous shift of traditionally state cases into federal courts."); *see also Pennsylvania v. Eli Lilly & Co.*, 511 F. Supp. 2d 576, 585 (E.D. Pa. 2007) ("There is no meaningful indication that Congress intended to confer federal jurisdiction over state law causes of action implicating the federal statutes involved here, namely the FDCA and Title XIX of the Social Security Act . . . .").

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[3] In *Merrell Dow*, the plaintiffs alleged that the drug "Bendectin" was misbranded in violation of the FDCA because its labeling did not provide adequate warning that its use was potentially dangerous. *Id*. at 805-06.

The cases relied on by defendants are distinguishable. In *In re: Epogen & Aranesp Off-Label Marketing & Sales Practice Litigation*, 590 F. Supp. 2d 1282 (C.D. Cal. 2008), a consumer class brought RICO and California claims alleging that a drug manufacturer and other defendants engaged in a fraudulent scheme that caused the class to pay millions of dollars for drugs prescribed for ineffective and unsafe off-label purposes. The court held that to the extent the plaintiffs' claims were solely based on alleged violations of the FDCA, those claims were an impermissible attempt to bring a private suit for violation of the FDCA. *Id*. at 1290. The court also held, however, that "some false statements made in connection with prescription drug marketing are actionable under state or federal law, even if their truth may be generally within the purview of the FDA." *Id*. at 1291 (internal quotation and citation omitted). Here, plaintiff's UCL and FAL claims are not solely based on the alleged FDCA violations, and instead the gravamen of those claims is that defendants falsely stated that Tracleer and Ventavis were an appropriate combination therapy. *In re: Zyprexa Products Liability Litigation*, 04-MD-1596, 07-CV-1933 (JBW), 2008 U.S. Dist. LEXIS 10355 (Feb. 12, 2008 E.D.N.Y.), is also distinguishable. There, the court presiding over multidistrict litigation involving the drug Zyprexa, exercised jurisdiction over a case alleging solely state law claims that Eli Lilly devised elaborate schemes to market the drug for off label uses. The court found that the state law claims implicated the federal Medicaid laws, and that "[a]t issue here is not simply a federal drug standard, but the factor of an intricate federal regulatory medicine scheme [including] detailed federal funding provisions, requiring some degree of national uniformity in interpretation." *Id*. at *16-17.

III. Preemption

Finally, defendants contend that removal is proper because the FDCA completely[4] preempts plaintiff's UCL and FAL claims. The Supreme Court has explained that complete preemption, which provides a basis for removal, occurs when the "pre-emptive force of a statute is so 'extraordinary' that it 'converts an ordinary state common-law complaint into one stating a federal claim for purposes of the

[4] Confusingly, defendants assert that the "FDCA completely preempts Asahi's claims" Opposition at 15:10 and also that "Actelion Pharmaceuticals US, Inc. does not argue that the FDCA completely pre-empts all state law claims." *Id*. at 15:23.

well-pleaded complaint rule.'" *Caterpillar Inc. v. Williams*, 482 U.S. 386, 393 (1986). In contrast, "a case may not be removed to federal court on the basis of a federal defense, including the defense of pre-emption, even if the defense is anticipated in the plaintiff's complaint, and even if both parties concede that the federal defense is the only question truly at issue." *Id*.

Defendants do not cite any authority for the proposition that the FDCA completely preempts state law claims. To date, the Supreme Court has found only three instances where a federal statute "wholly displaces the state-law cause of action through complete pre-emption": the Labor-Management Relations Act, the Employee Retirement Income Security Act, and the National Bank Act. *See Beneficial Nat. Bank v. Anderson*, 539 U.S. 1, 8-10 (2003); *see also U.S. Airways Master Exec., Council v. Amer. West Master Exec. Council*, 525 F. Supp. 2d 127, 133-34 (D.D.C. 2007). In contrast, plaintiffs cite a number of cases in which courts recognize that the FDCA does not completely preempt state law. *See Pennsylvania v. Eli Lilly & Co.*, 511 F. Supp. 2d. 576, 581 (E.D. Pa. 2007); *Tofanelli v. Biogen Idec, Inc.*, Civ. No. 07-11840-DPW, 2008 WL 3824775, at *3 (D. Mass. Aug. 5, 2008). In the face of this authority, the Court declines to hold that the FDCA, which notably does not provide for a private right of action, so "wholly displaces" state law that it completely pre-empts state law.

Although couched as a "complete preemption" argument, in actuality defendants' contention that the FDCA preempts plaintiffs' UCL and FAL claims is one of defensive preemption. Defendants argue that plaintiffs' UCL and FAL claims seek to enforce the FDCA and its implementing regulations, and that Congress has exclusively granted such enforcement to the FDA. Defendants may raise this contention as a defense to plaintiffs' claims in state court. *See Caterpillar*, 482 U.S. at 393; *see also Gile v. Optical Radiation Corp.*, 22 F.3d 540, 543 (3d Cir. 1994) (affirming dismissal of state tort claims because such claims were preempted under Medical Device Amendments to FDCA).

CONCLUSION

For the foregoing reasons, the Court concludes that there is no basis for federal jurisdiction, and GRANTS plaintiff's motion to remand and REMANDS this case to the Superior Court for the County of San Mateo. Because the Court lacks jurisdiction over this case, the Court does not address defendants' motion to dismiss for lack of personal jurisdiction.

It is a close call whether to grant plaintiffs' request for attorneys' fees. However, based on defense counsel's arguments at the hearing, as well as all the pleadings in the action, the Court finds that it would not be appropriate to award fees. Accordingly, the Court DENIES plaintiff's request for attorneys' fees and costs. The Court DENIES all other pending motions as moot.

IT IS SO ORDERED.

Dated: March 25, 2009

SUSAN ILLSTON
United States District Judge